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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,594	01/05/2006	Alain Prochiantz	275010US0XPCT	1972
22850	7590	02/20/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER BURKHART, MICHAEL D	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 02/20/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/541,594	Applicant(s) PROCHIANTZ ET AL.	
	Examiner MICHAEL BURKHART	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt and entry of the amendment dated 11/22/2008 is acknowledged. After entry of the amendment, claims 1-15 are pending, claims 1-6 and 10-15 remain withdrawn. Claims 7-9 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Divida et al (WO 02/10201, cited by applicants) in view of Schutze-Redelmeier et al (1996, J. Immunol.) as evidenced by Derossi et al (1998, cited by applicants). **This is a new rejection necessitated by amendment of the claims in the response filed 11/22/2008. Specifically, the claims no**

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require that a transducing peptide be adsorbed to the cargo, a limitation not previously recited.

Divida et al teach transducing peptides that associate non-covalently to a compound of interest, i.e. a cargo, such as peptides and oligonucleotides. Such peptides and oligonucleotides are inherently less than 1 μm in size for reasons set forth in the previous Office Action (35 USC 102 rejection, page 1). This association is considered to be "adsorbed" to (e.g. bound to the surface) the cargo, absent a limiting definition of adsorbed in the instant specification. See page 3, second and third full ¶'s. Pharmaceutical compositions are disclosed on page 5. The transducing peptides of Divida et al comprised hydrophobic domains that interacted with cargo peptides through hydrophobic contacts and interactions (pages 72 - 74).

Divida et al do not teach using a transducing peptide of the penetratin family.

Schutze-Redelmeier et al teach the antennapedia homeodomain (AntpHD), in particular its third helix, can be used to translocate peptides and oligonucleotides into cells (abstract, and ¶ linking pages 650-651). The AntpHD inherently comprises a third helix, responsible for transduction, that comprises a highly hydrophobic domain, I-W-F, and what is considered another hydrophobic domain, M-K-W (see Figure 1 of Derossi et al) according to the description of such by Divida et al (page 12). Regarding claim 8, a review of the Sequence Listing reveals SEQ ID NO: 2 to be a 16-mer peptide that requires only a tryptophan (W) at position 6. This is because the Sequence Listing states that "Xaa" at positions 1-5 and 7-16 "can be any naturally occurring amino acid". The AntpHD third helix (residues 43-58 in Figure 1 of Derossi et al) comprises such a 16-mer.

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The claimed composition is essentially disclosed by Divida et al with the exception of the use of a penetratin family peptide. The ordinary skilled artisan, seeking a compositions to deliver compounds to cells, would have been motivated to use a penetratin family peptide with the compositions and methods of Divida et al because Schutze-Redelmeier et al teach such penetratin peptides to be a well known type of transducing peptide that have utility for delivering compounds to cells. It would have been obvious for the skilled artisan to do this because of the known benefit of delivering compounds to cells as taught by Schutze-Redelmeier and Divida et al. Furthermore, all of the claimed elements were known in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention (*See KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)).

Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim Rejections - 35 USC § 112

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising transducing peptides known in the prior art, does not reasonably provide enablement for compositions comprising the broad genus of transducing peptides encompassed by the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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or use the invention commensurate in scope with these claims. **This rejection is maintained for reasons made of record in the Office Action dated 5/30/2008, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 11/22/2008 have been fully considered but they are not persuasive. Applicants essentially assert that the claims have been amended to recite subject matter indicated as enabled, i.e. the peptides of the penetratin family are well known in the art.

Such is not the case. The term "peptides of the penetratin family" is not defined in the specification and thus is given a reasonably broad interpretation to include derivatives, mutations, deletions, etc. of the known transducing peptides. The potential breadth of such peptides, in light of claim 8, is very large for reasons made of record, primarily because SEQ ID NO: 2 requires little more than a tryptophan residue at position six (and thus encompasses up to 20¹⁵ possible sequences). The prior art documents cited by applicants, e.g. the 6,080,724 patent add little to what has already been discussed regarding functional penetratin transducing peptides in light of the breadth of the claims. The '724 patent teaches little more than what is taught in Derossi and Joliot et al (both of record): the penetratin peptide based upon the wild-type sequence of the Antennapedia third helix (i.e. 43-58 in Fig. 1 of Derossi) functions as a transducing peptide, as do some peptides with mild substitutions at certain residues. Alteration of the Trp residues abolishes the transduction ability (i.e. the Phe 48, 58 peptide). This does not begin to cover the scope of transducing peptides encompassed by the instant claims for reason of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhardt/
Primary Examiner, Art Unit 1633